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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/185,732    11/04/98    BARROWS    T    09125/001001

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HM12/1220

EXAMINER

RUSSEL, J

ART UNIT

PAPER NUMBER

1654

DATE MAILED:

12/20/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/185,173

Applicant(s)

J. Barrows et al

Examiner

J. Russel

Group Art Unit

1654

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 9-30-1999.
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-162 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-162 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 4 ☒ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other \_\_\_\_\_

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1. The consent of assignee to the reissue and the offer to surrender have been received.

The request for transfer of original drawings has been received. This request will be treated as a request to transfer the formal drawings from the original patent file to the reissue application. See MPEP 1413.

The copy of the Certificate of Correction correcting the inventorship of the application has been received.

The corrected copy of the page of the specification corresponding to column 3 of the patent has been received and entered.

Applicant is reminded of the continuing obligation under 37 CFR 1.56 to timely apprise the Office of any litigation information, or other prior or concurrent proceeding, involving Patent No. 5,583,114, which is material to patentability of the claims under consideration in this reissue application. This obligation rests with each individual associated with the filing and prosecution of this application for reissue. See MPEP §§ 1404, 1442.01 and 1442.04.

2. The supplemental reissue oath/declaration filed September 30, 1999 is defective because it was not dated by inventor Barrows. See 37 CFR 1.175(a)(1) and MPEP § 1414.

Claims 1-162 rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175 and MPEP 1444.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

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This rejection and the requirement for a reissue declaration under 35 U.S.C. 251 will be overcome once the copy of the supplemental reissue oath/declaration signed and dated by inventor Barrows is received and entered into the application.

3. Claims 18-162 are rejected under 35 U.S.C. 251 as being an improper recapture of claimed subject matter deliberately canceled in the application for the patent upon which the present reissue is based. As stated in *Ball Corp. v. United States*, 221 USPQ 289, 295 (Fed. Cir. 1984):

The recapture rule bars the patentee from acquiring, through reissue, claims that are of the same or broader scope than those claims that were canceled from the original application.

Claims 18-162 are broader in scope than the patented method claims in terms of the protein, protein concentration, crosslinking agent concentration, and burst strength limitation. In particular, the patented method claims require the use of serum albumin, whereas the new claims added in this reissue application permit the use of any albumin. The patented method claims require a protein concentration of about 20-60 wt/vol %, whereas the new claims added in this reissue application permit the use of any concentration of protein. The patented method claims require a crosslinking agent concentration of about 50-800 mg/ml, whereas the new claims added in this reissue application permit the use of any concentration of crosslinking agent. The patented method claims require a burst strength of greater than about 10 mmHg, whereas the new claims added in this reissue application permit any burst strength. These limitations were inserted into the claims eventually allowed in the patent by the amendment filed June 12, 1995 in order to overcome a prior art rejection. In particular, the remarks accompanying the amendment filed June

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12, 1995 (see, e.g., page 7, line 7, and page 8, lines 2-5) and the further remarks filed January 24, 1996 (see, e.g., page 2, line 20, and page 3, lines 2-5) in response to another prior art rejection refer to these limitations as helping to distinguish over the prior art on the basis of a patentable difference in terms of composition and characteristics of the composition. It is impermissible to claim subject matter in a reissue application which was intentionally canceled during prosecution of the patent application in order to obtain the patent. See also *In re Clement*, 45 USPQ2d 1161 (CAFC 1997).

4. The amendment filed September 30, 1999 proposes amendments to claims 1 and 17 that do not comply with 37 CFR 1.121(b), which sets forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required.

In particular, at claim 1, last line, of the amendment filed September 30, 1999, "than" was changed to "then" without the change being marked as required by 37 CFR 1.121(b). At claim 17, line 16, of the amendment filed September 30, 1999, a comma was deleted from after "formula" without the change being marked as required by 37 CFR 1.121(b). At claim 17, page 4 of the amendment filed September 30, 1999, line 2, "diradical" was changed to "radical" without the change being marked as required by 37 CFR 1.121(b).

5. Applicant's arguments filed September 30, 1999 have been fully considered but they are not persuasive.

The new matter rejection under 35 U.S.C. 251 and the rejection under 35 U.S.C. 112, first paragraph, are withdrawn. The rejections concerning "albumin" were withdrawn during the

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interview of September 13-14, 1999, for the reasons summarized at pages 10-11 of the Applicants' response filed September 30, 1999. The rejections concerning the peel strength ranges and the burst strength ranges are withdrawn because, as discussed in the interview of September 13-14, 1999, *Ralston Purina Co. v. Far-Mar Co*, 227 USPQ 177 (CAFC 1985) is more applicable to the instant fact situation than is *In re Wertheim*, 209 USPQ 554 (CCPA 1981). The rejections concerning the oligomeric diradical formula are overcome by the amendments to the claims. The rejections concerning the crosslinking agent concentration range are overcome by the amendments to the claims.

The rejection of claims 18-162 under 35 U.S.C. 251 as being an improper recapture is maintained.

Applicants and the examiner are in agreement that these reissue claims are broader in scope than the patent claims. Applicants and the examiner are also in agreement that these reissue claims are broader in some aspects but narrower in other aspects than canceled or amended claims in the parent application, and are in agreement that the newly added reissue claims are narrower than the broadest canceled claim in the parent application in at least one aspect, i.e. the identity of the protein, relevant to the prior art rejections in the original prosecution. Applicants and examiner are in agreement that *In re Clement*, 45 USPQ2d 1161 (CAFC 1997) is the most recent and most relevant controlling authority. (The examiner does not have access to the F.3d publication of Clement, and must cite using the USPQ2d paginations.) Applicants and the examiner disagree on the necessity of comparing the reissue claims with the broadest claims

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canceled during prosecution of the parent application. Note that Clement at page 1164, last paragraph, states that comparing the reissue claim with the canceled claim “is one way to do this”, which implies that such a comparison is not the only way to determine recapture. Ultimately, Applicants’ argument for the need of this comparison can not be accepted because Clement explicitly refuses to perform this analysis (see page 1166, third and fourth full paragraphs). That the reissue claims in Clement may have been intermediate in scope between the originally-filed application claims and the patent claims did not override clear indications in the prosecution history that Applicants intended to abandon subject matter in order to obtain the patent. Further, in the court’s two summaries of its recapture analysis (see page 1166, first full paragraph: “On balance, reissue claim 49 is broader than it is narrower in a manner directly pertinent to the subject matter that Clement surrendered throughout the prosecution. Even with the additional limitations, claims 50-52 are also broader than they are narrower in a manner directly pertinent to the subject matter that Clement surrendered during prosecution”; and see page 1166, last paragraph: “We agree with the board’s conclusion that the reissue claims are broader than the patent claims in a manner directly pertinent to the subject matter that Clement surrendered during prosecution.”), the analysis is limited to the reissue claims, the patent claims, and the subject matter surrendered during prosecution of the parent application. The final analysis does not mention the canceled claims.

The examiner maintains his position that during prosecution of the parent application, Applicants surrendered subject matter with respect to protein, protein concentration, crosslinking

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agent concentration, and burst strength. As noted by Applicants, Clement requires that "To determine whether an applicant surrendered particular subject matter, we look to the prosecution history for arguments and changes to the claims made in an effort to overcome a prior art rejection." During the prosecution of the application that led to the patent, Applicants inserted limitations on the protein, protein concentration, crosslinking agent concentration, and burst strength in response to prior art rejections. In the parent application, there are arguments on the record explicitly referring to the serum albumin and the burst strength limitations as establishing patentability over the prior art, which is further evidence of Applicants' surrender of subject matter. The insertion and argument of these limitations in response to a prior art rejection constitutes deliberate surrender of the subject matter not embraced by these limitations.

Equitable and fairness considerations do not override the statutory requirement that a reissue application must be based upon error. Deliberate surrender of subject matter in order to obtain a patent does not constitute error which can be corrected by reissue.

If, for example, claim 18 were to be amended to require about 20-60 wt/vol % serum albumin, about 50-800 mg/ml of the crosslinking agent, and a burst strength greater than about 10 mmHg, this claim would not be subject to rejection under 35 U.S.C. 251 as being an improper recapture because it would contain those limitations inserted into the claims during prosecution of the parent application order to avoid the prior art. Note also that this claim would be broader in some aspects than the patent claims, and broader in some aspects than the broadest canceled claims in the parent application. However, those aspects in which the claim is broader were not

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surrendered during prosecution of the parent application in order to obtain the patent, and thus would not constitute improper recapture.

The rejection under 35 U.S.C. 112, second paragraph, set forth in the previous Office action is withdrawn in view of the amendments to the claims, and, with respect to claim 157, for the reason given in Applicants' remarks.

The claim objections set forth in paragraphs 9 and 10 of the previous Office action are withdrawn in view of the amendments to the claims.

The prior art rejections over Doi et al set forth in the previous Office action are withdrawn for the reasons given by Applicants in their remarks.

6. The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

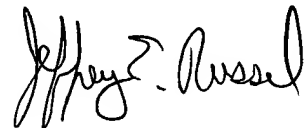
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Michael Woodward can be reached at (703) 308-4028. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 305-7401 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

November 30, 1999